

KIMBERLY LAMBERT ADAMS RACHAEL R. GILMER BRIAN H. BARR MICHAEL C. BIXBY M. ROBERT BLANCHARD BRANDON L. BOGLE W. TROY BOUK WESLEY A. BOWDEN VIRGINIA M. BUCHANAN WILLIAM F. CASH III IEFF GADDY REBECCA D. GILLILAND (LICENSED ONLY IN ALABAMA)

FREDRIC G. LEVIN MARTIN H. LEVIN ROBERT M. LOEHR STEPHEN A. LUONGO M. JUSTIN LUSKO NEIL E. McWILLIAMS, JR. CLAY MITCHELL PETER J. MOUGEY DANIEL A. NIGH TIMOTHY M. O'BRIEN

MIKE PAPANTONIO CHRISTOPHER G. PAULOS EMMIE I. PAULOS A. RENEE PRESTON ROBERT E. PRICE MARK J. PROCTOR TROY A. RAFFERTY MATTHEW D. SCHULTZ W. CAMERON STEPHENSON THOMAS A. TAYLOR LEO A. THOMAS **BRETT VIGODSKY** 

OF COUNSEL: LAURA S. DUNNING (LICENSED ONLY IN ALABAMA) BEN W. GORDON, JR. ARCHIE C. LAMB, JR. PAGE A. POERSCHKE (LICENSED ONLY IN ALABAMA) CHRISTOPHER V. TISI (LICENSED IN WASHINGTON, D.C. AND MARYLAND)

LEFFERTS L. MABIE, JR. (1925-1996) D.L. MIDDLEBROOKS (1926-1997) DAVID H. LEVIN (1928-2002) STANLEY B. LEVIN (1938-2009)

## RE: MDL 2804: SECOND AMENDED NOTICE OF ARCOS DISCLOSURE

## Dear Counsel:

You are receiving this letter from the Plaintiffs' Executive Committee of In re National Opioid Prescription Litigation, MDL No. 2804. This letter explains how you may obtain, without charge, refined data that shows in detail everything we know from the ARCOS database regarding which opioids flowed into your clients' jurisdictions, and how they got there.

By way of background, ARCOS (Automation of Reports and Consolidated Orders System) is an automated, comprehensive drug reporting system administered by the DEA which monitors the flow of controlled substances from (1) their point of manufacture through (2) commercial distribution channels to (3) point of sale or dissemination at the dispensing/retail level (such as hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions). All DEA registrants who manufacture and/or distribute controlled substances are required to report to ARCOS.

In the MDL litigation, the DEA produced a subset of ARCOS Data reflecting all transactions nationally by every registered manufacturer and distributor of opioid drug products. In total, the ARCOS Data produced by the DEA has 500,709,803 transaction records. In order for the data to be useful, the Opioid MDL Executive Committee hired a strategic litigation consulting group out of Washington, D.C. to process, validate and augment the opioid ARCOS data. In doing so, the consulting group made certain corrections to and exclusions from the county-level processed ARCOS data, which are explained in the attached **Appendix**.

Pursuant to agreement with the DEA and by order of the federal MDL Judge, the Honorable Dan A. Polster, the MDL PEC is making available to you without charge the unprocessed ARCOS data in the same format it was received from the DEA. This data is what you would receive if you filed a *Touhy Request* with the DEA.

The PEC has found, however, that the data was not useful as received, so we spent extensive resources making it useful. We are also providing you, again without charge, access to the result of that investment. The PEC's ARCOS website allows you to go straight to the county-level processed ARCOS data and county-level reports and download the information you need in order to understand from the ARCOS database exactly which opioid products flowed into your clients' jurisdictions and how they got there. While you have the right to download the unprocessed ARCOS data and process it yourself, we urge you to avoid that step and instead simply access the PEC's processed ARCOS data and reports.

To obtain either the unprocessed ARCOS data or access to the PEC's ARCOS website, please contact ARCOSRequest@levinlaw.com.

Sincerely,

Peter J. Mougey

On Behalf of the Plaintiffs' Executive

Committee

## **Appendix: Exclusions/Corrections to the ARCOS Data Reflected in the County-Level Reports**

- a. Duplicate transactions are excluded when the same transaction was reported to ARCOS more than once by the same registrant. <sup>1</sup>
- b. Transactions are excluded where the Drug Code from the NDC dictionary is not one of the 14 opioids tracked by the DEA.
- c. Transactions are excluded when the Action Indicator code, Correction Number, or both suggest the reported transaction is erroneous.
- d. All transactions involving reverse distributors, analytical labs, importers, exporters, or researchers are excluded.
- e. Transactions between two registrants are excluded when the transaction is reported by the registrant *receiving* the shipment, because the transaction was already reported to ARCOS by the registrant *sending* the shipment.
- f. Transactions with obvious errors in the reported Quantity are excluded.
- g. Transactions with Transaction Code "X" (Lost-in- Transit) are excluded, because "Transaction Code X" is an explanatory code which does not affect an ARCOS registrant's inventory.<sup>2</sup>
- h. The Calculated Base Weight in Grams was corrected when it was calculated using an incorrect Ingredient Base Weight from the NDC dictionary.

<sup>&</sup>lt;sup>1</sup> The ARCOS Data had 610,381 duplicate transactions in December 2007 for one of the Cardinal Health distribution centers (Seller DEA Number: RC0221236). All but one of each set of exact duplicate transactions was excluded.

<sup>&</sup>lt;sup>2</sup> ARCOS Handbook, §5.8.3, p. 5-19.

- i. Where the ARCOS Data (NDC, Drug Code, and Drug Name) differed from the NDC Dictionarythe ARCOS Data was updated to reflect the information in the November 2018 NDC Dictionary.<sup>3</sup>
- j. For clarity, the trade name of the drug product ("Trade/Product Name") and the dosage form ("Package Measure") were added to the ARCOS Data using the NDC Dictionary.
- k. Deletion requests and originally-reported transactions are excluded where: (1) they cancel each other out, or (2) the ARCOS Data already includes an adjusted or corrected transaction.

<sup>&</sup>lt;sup>3</sup> The DEA's NDC dictionary is available at www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt. The dictionary is explained at www.deadiversion.usdoj.gov/arcos/ndc/readme.txt. The DEA updates the NDC dictionary monthly to correct errors, add new drug products, and remove discontinued drug products. The consultant used the NDC dictionary updated on November 1, 2018, plus any discontinued drug products from earlier versions of the NDC dictionary in May 2018 –October 2018. An alternative NDC dictionary is maintained by the FDA (<a href="www.accessdata.fda.gov/scripts/cder/ndc/index.cfm">www.accessdata.fda.gov/scripts/cder/ndc/index.cfm</a>).